UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
ROCKINGHAM DIVISION
Case No.: 1:14-cv-00682

Shelley Harris, Plaintiff, vs. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	**FIRST AMENDED COMPLAINT**

COMES NOW Plaintiff, Shelley Harris, by and through undersigned counsel, and for her cause of action files this First Amended Complaint for damages against the above-named Defendant alleging the following:

INTRODUCTION

1. This is a civil action for products liability alleging personal injuries and damages, including serious withdrawal symptoms, suffered by Plaintiff Shelley Harris (hereinafter, "Plaintiff") as a direct and proximate result of her ingestion and cessation of the prescription drug, Cymbalta (duloxetine), which is manufactured, marketed, and sold by Defendant Eli Lilly and Company (hereinafter, "Defendant" or "Lilly"). This civil action alleges that Plaintiff's personal injuries and damages were suffered as a result of Lilly's failure to adequately warn physicians and consumers about the frequency, severity, and/or duration of symptoms associated with discontinuation of Cymbalta (throughout, interchangeably "discontinuation" or "withdrawal" "symptoms" or "syndrome"); warn physicians and consumers about the general ineffectiveness of tapering Cymbalta with the dosages of Cymbalta made available by Lilly to avoid or mitigate discontinuation or withdrawal symptoms; and instruct physicians and consumers as to the most

safe and effective way to taper Cymbalta with the dosages of Cymbalta made available by Lilly to avoid or mitigate discontinuation or withdrawal symptoms. Plaintiff's claims sound in negligence, fraud, concealment, and breach of warranty.

PARTIES

2. Plaintiff is, and at all times relevant to this Complaint was, a citizen of the State of North Carolina and resident of Moore County.

3. Defendant Eli Lilly and Company is, and at all times relevant to this Complaint was, an Indiana corporation with its headquarters in Indianapolis, Indiana. Lilly is a pharmaceutical company involved in the research, development, testing, manufacture, production, promotion, distribution, marketing, and sale of numerous pharmaceutical products, including Cymbalta.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C.A. § 1332. There is complete diversity of citizenship between Plaintiff and Lilly and the amount in controversy exceeds $75,000.00.

5. This Court has personal jurisdiction over Lilly because Lilly has substantial contacts with, and has purposefully marketed and sold Cymbalta and numerous other pharmaceutical products in, the State of North Carolina, such that maintenance of the action in this Court is consistent with traditional notions of fair play and substantial justice.

6. Furthermore, Lilly has caused tortious injury by acts and omissions in the State of North Carolina, while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving substantial revenue from goods used or consumed and services rendered in the State of North Carolina.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391. A substantial portion of the events giving rise to the claims alleged in this Complaint took place in this district.

FACTUAL ALLEGATIONS

8. Lilly is one of the largest pharmaceutical companies in the world with annual revenues exceeding $20 billion. From 2004 through 2014, a substantial portion of Lilly's revenue was derived from its drug Cymbalta, whose 2013 annual sales exceeded $3 billion domestically and $5 billion worldwide.

9. Lilly has enjoyed considerable financial success from manufacturing and selling prescription drugs for the treatment of clinical depression, including the popular antidepressant Prozac (generically known as fluoxetine). Lilly launched Prozac in 1988, touting it as the first "Selective Serotonin Reuptake Inhibitor" ("SSRI"). SSRIs are a class of antidepressant drugs that have been promoted as increasing the brain chemical serotonin in the synaptic clefts between the neurons in the brain. Prozac became extremely popular in the 1990s and was the top-selling antidepressant of its kind. Prozac's patent expired in August 2001, leading to a proliferation of generic versions of the drug.

10. In 2001, Lilly needed to fill the void left behind by Prozac's patent expiration, and so it sought approval by the Food and Drug Administration ("FDA") for its next patented antidepressant, Cymbalta. Cymbalta belongs to a class of antidepressants known as "Serotonin and Norepinephrine Reuptake Inhibitors" ("SNRIs"). SNRIs are similar to SSRIs, but in addition to blocking the absorption of serotonin, SNRIs are thought to block the absorption of another neurotransmitter, norepinephrine, thereby increasing the levels of both serotonin and norepinephrine in the brain. These drugs are promoted as treatments for pain as well as depression.

11. The FDA initially rejected Lilly's application in 2003 for approval of Cymbalta due to certain violations of good manufacturing practices and the risk of liver toxicity apparent in the drug's safety profile.

12. Eventually, in 2004, the FDA approved Cymbalta with a liver toxicity warning included in the prescribing information. The drug was approved for Major Depressive Disorder ("MDD"). In 2007, the FDA approved Cymbalta for treatment of Generalized Anxiety Disorder ("GAD") and in 2008 for treatment of fibromyalgia.

13. Since the FDA's initial approval of Cymbalta in 2004, Lilly has aggressively marketed the drug to the public and the medical community, spending millions of dollars each year on advertising and promotion. Lilly has promoted Cymbalta directly to consumers, including Plaintiff, through various media platforms, including internet, print and television. In addition, Lilly has promoted Cymbalta to the medical community by utilizing its well-organized army of sales representatives to personally visit physicians and health care professionals to distribute free drug samples and promotional literature. Lilly further promoted Cymbalta through advertisements in medical journals and presenting talks and exhibits at medical conferences.

14. Lilly's promotional campaigns have continuously failed to provide adequate instructions to users and health care professionals for stopping Cymbalta and have failed to include adequate warnings that fully and accurately inform users and health care professionals about the frequency, severity, and/or duration of Cymbalta withdrawal, warn physicians and consumers about the general ineffectiveness of tapering Cymbalta with the dosages of Cymbalta made available by Lilly to avoid or mitigate discontinuation or withdrawal symptoms; and instruct physicians and consumers as to the most safe and effective way to taper Cymbalta with the dosages of Cymbalta made available by Lilly to avoid or mitigate discontinuation or withdrawal symptoms.

15. Withdrawal symptoms are not connected to a patient's underlying condition but rather are the body's physical reactions to the drug leaving the system. While many SSRIs and SNRIs can cause withdrawal symptoms, the initiation, frequency, and severity of withdrawal symptoms correlate to a drug's half-life. The half-life of a drug is the time it takes for the concentration of the drug in the body to be reduced by half. This information is one of the basic pharmacokinetic properties of a drug and is known to researchers developing the drug. Cymbalta has one of the shortest half-lives of any of the SSRIs and SNRIs. Since 2004, the Cymbalta label has stated that the half-life of Cymbalta is approximately 12 hours. In contrast, the half-life of Prozac is seven days. The shorter the half-life, the faster the body eliminates the drug from the system, thus creating a higher risk of withdrawal symptoms. Because Cymbalta's half-life is less than one day and Cymbalta is generally administered once daily, it is possible for users of Cymbalta to experience withdrawal symptoms after simply forgetting to take one dose.

16. Despite Lilly's awareness of Cymbalta's half-life and the correlation between a short half-life and withdrawal risk, Lilly did not include any cross-references between the Pharmacokinetics section of the label and either the Precautions section or the Dosage and Use section. In fact, rather than drawing attention to the potential consequences of Cymbalta's extremely short half-life, Lilly misleadingly referenced all other SSRIs and SNRIs, as if Cymbalta could be expected to pose a similar risk of withdrawal as all other drugs of its class generally:

> During marketing of other SSRIs and SNRIs (Serotonin and Norepinephrine Reuptake Inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g. paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional liability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.

(2004 Cymbalta label.) The extremely short half-life of Cymbalta should have alerted Lilly's researchers to the fact that the risk of Cymbalta withdrawal would be more frequent than that experienced with other SSRIs and SNRIs.

17. Lilly should have been aware of the significance of antidepressant withdrawal, because Lilly had previously researched and publicized the issue in connection with its antidepressant Prozac. Because Prozac has an extremely long half-life relative to other antidepressants, the length of time it takes for a person's body to fully eliminate Prozac from the system provides a built-in gradual tapering of sorts, so that withdrawal symptoms from Prozac are relatively infrequent. Prozac's main competitors in the 1990s, Zoloft and Paxil, had shorter half-lives, and Lilly engineered a campaign to differentiate Prozac from its competitors on this basis, funding clinical studies of antidepressant withdrawal and coining the term "antidepressant discontinuation syndrome."

18. Researchers, including Lilly's own consultants, have postulated that withdrawal reactions result from a sudden decrease in the availability of synaptic serotonin in the face of down-regulated serotonin receptors. *See* Schatzberg et al., Possible mechanisms of the serotonin reuptake inhibitor discontinuation syndrome, J. Clin Psychiatry 58 (suppl7): 23-7 (1997); Blier and Tremblay, Physiological mechanisms underlying the anti-depressant discontinuation syndrome, J Clin Psychiatry 67 (suppl4) (2006): 8-13. They have theorized that, upon chronic dosing, the increased occupancy of pre-synaptic serotonin receptors signals the pre-synaptic neuron to synthesize and release less serotonin. Serotonin levels within the synapse drop, then rise again, ultimately leading to down-regulation of post-synaptic serotonin receptors. In other words, as SSRIs and SNRIs block the reuptake of serotonin and norepinephrine, structural changes in the brain occur such that production of these neurotransmitters is reduced. These changes in the

brain's architecture may contribute to withdrawal symptoms, as a patient is, upon cessation of the drug, left not only with the absence of the drug but also structural changes in the brain that remain for some time even after the drug has fully washed out of the person's system. Because of the short half-life of Cymbalta, the brain has even less time to adjust to the cessation of Cymbalta treatment. Despite Lilly's knowledge of this phenomenon, Lilly did not include in Cymbalta's label or promotional materials any information regarding the increased risk of withdrawal due to structural changes in the brain exacerbated by Cymbalta's short half-life.

19. In 2004, when Cymbalta was introduced in the United States market, Lilly's physician labeling (United States Package Insert, or "USPI") for Cymbalta stated the following with respect to discontinuation or withdrawal symptoms: :

> Discontinuation of Treatment with Cymbalta- Discontinuation symptoms have been systematically evaluated in patients taking Cymbalta. Following abrupt discontinuation in placebo controlled clinical trials of up to 9-weeks duration, the following symptoms occurred at a rate **greater than or equal to 2%** and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness; nausea; headache; paresthesia; vomiting; irritability; and nightmare.

(emphasis added). Cymbalta's label also provided the following instructions for stopping Cymbalta:

> A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

Id.

20. In 2007, Lilly changed the discontinuation precaution section of the USPI to state that symptoms occurred in Cymbalta users at a rate of "**greater than or equal to 1%**" (emphasis added).

21. By the time of the 2011 iteration of the USPI, Lilly had changed the language to state that these symptoms occurred at "**1% or greater**." (emphasis added).

22. In addition to using the euphemistic term "discontinuation" in both its USPI and patient Medication Guide to describe Cymbalta's withdrawal symptoms, the label did not accurately reflect that a significant percentage of Cymbalta users suffered from withdrawal symptoms. Rather, the warnings suggested that Cymbalta withdrawal was rare, occurring at a rate of approximately only 1% or 2%.

23. However, Lilly's own studies, published in a January 2005 article in the Journal of Affective Disorders, showed that, at a minimum, between 44.3% and 50% of Cymbalta patients suffered from "discontinuation" side effects. The article also noted that the withdrawal symptom data compiled during Lilly's clinical trials was gathered from "spontaneous reports" of symptoms (patients volunteering symptoms) and not using the more accurate "symptom checklist." The authors acknowledged that use of a symptom checklist would likely produce even higher incidence rates of withdrawal symptoms. David G. Perahia et al., Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder, 89 JOURNAL OF AFFECTIVE DISORDERS 207 (2005).

24. Lilly has never disclosed this critical data in its USPI or its patient Medication Guide. In comparison, Lilly's European label disclosed that withdrawal symptoms occur in approximately 45% of patients upon discontinuation of Cymbalta. Moreover, Lilly's European label disclosed that patients may suffer withdrawal symptoms from an "inadvertently missed" dose. Lilly has never disclosed this fact in its USPI or its patient Medication Guide.

25. Instead of disclosing the incidence rate for discontinuation or withdrawal syndrome as an aggregate constellation of symptoms in the United States, Lilly's USPI has always provided

merely a "frequency threshold" (of 1% or 2%) for individual symptoms, misleadingly suggesting that Cymbalta withdrawal syndrome is rare or infrequent.

26. Moreover, Lilly's clinical trials showed that, overall, between 9.6% and 17.2% of Cymbalta users suffered *severe* withdrawal symptoms, *id.*, yet Lilly has never informed United States physicians or patients of that risk.

27. Cymbalta's withdrawal symptoms include, among other things, headaches, dizziness, nausea, fatigue, diarrhea, paresthesia, vomiting, irritability, nightmares, insomnia, anxiety, hyperhidrosis, sensory disturbances, electric shock sensations, seizures, and vertigo. When patients try to stop taking Cymbalta, the symptoms can be severe enough to force them to start taking Cymbalta again, not to treat their underlying conditions, but simply to stop the withdrawal symptoms. Patients thus become prisoners to Cymbalta, and Lilly financially benefits by having a legion of physically dependent, long-term users of Cymbalta.

28. Despite Lilly's knowledge of the high rate of withdrawal symptoms in patients stopping Cymbalta, Lilly neither provided adequate instructions to patients and physicians for stopping Cymbalta nor included adequate warnings in its product label, marketing, or advertising to fully and accurately inform patients and physicians about the frequency, severity, and/or duration of the withdrawal symptoms.

29. Lilly's misleading direct-to-consumer promotional campaigns and its failure to adequately warn patients and physicians about the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms have paid off financially for Lilly. Cymbalta became a "blockbuster" drug with over $3.9 billion dollars in annual sales. In the past few years, Cymbalta has either been the most profitable or second most profitable drug in Lilly's product line. Lilly had the knowledge, the means, and the duty to provide adequate instructions for stopping Cymbalta

and adequate warnings about the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms. Lilly could have relayed these instructions and warnings through the same means it utilized to promote its products, which included but are not limited to its labeling, "Dear Doctor letters," advertisements, and sales representatives.

30. Additionally, although Lilly recommended "gradual reduction," it provided no information as to what that might mean for patients taking Cymbalta and their physicians. Lilly did not, for example, provide any information in the United States label regarding the recommended time period, as it did in its European Cymbalta label, which stated, "It is therefore advised that duloxetine should be gradually tapered when discontinuing treatment over a period of *no less than 2 weeks*[.]" 2014 Cymbalta European Medicines Agency Label (emphasis added). Lilly also did not, for example, recommend dosing increments to follow when reducing the dose.

31. And, even though Lilly advised that the reduction in dose may be done at "a more gradual rate" if "intolerable" symptoms occur, Lilly failed to warn patients and physicians that its design of Cymbalta makes it impossible for "a more gradual rate" to be achieved, because the only available decreases are in 10 mg increments, with no "gradual reduction" possible once 20 mg is reached.

32. As Lilly was fully aware of the issue of antidepressant withdrawal and of Cymbalta's elevated withdrawal risk, Lilly should have included a strong warning that adequately informed patients and physicians that Cymbalta's design would not easily allow for a gradual tapering off of the drug (e.g., decreasing the dosage of Cymbalta in increments of 10 mgs) and an avoidance or mitigation of discontinuation or withdrawal symptoms. Cymbalta is manufactured as a delayed-release capsule filled with tiny beads at 20, 30 and 60 mg doses only, and Cymbalta's label and Medication Guide instruct physicians and patients that the capsule "should be swallowed

whole and should not be chewed or crushed, nor should the capsule be opened and its contents be sprinkled on food or mixed with liquids." Despite the clear inconsistency between Lilly's instructions to gradually taper off of Cymbalta and the lack of dosages below 20 mgs and between 30 and 60 mgs, Lilly failed to provide adequate instructions to physicians and patients as to the most safe and effective way to taper Cymbalta to avoid or mitigate discontinuation or withdrawal symptoms. In contrast, other SSRIs and SNRIs are available as scored tablets that can be halved and quartered with relative ease, or are available in liquid form which can be measured and dispensed in small increments.

33. Falsely reassured by the misleading manner in which Lilly reported Cymbalta's withdrawal symptoms, physicians, including Plaintiff's physician, have prescribed, and continue to prescribe, Cymbalta to patients without adequate instructions for stopping Cymbalta and without adequate warnings that fully and accurately inform them about the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms.

34. At all times relevant, Lilly knew or should have known of the significantly increased risk of withdrawal symptoms, including their severity and duration, posed by Cymbalta and yet failed to adequately warn about said risks.

35. At all times relevant, Lilly engaged in willful, wanton, and reckless conduct, including its failure to fully and accurately warn about the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms, all of which induced physicians to prescribe Cymbalta and patients to use it, including Plaintiff and Plaintiff's physicians.

36. Plaintiff's use of Cymbalta and consequent injuries and damages were a direct and proximate result of Lilly's acts and omissions relating to its failure to provide adequate instructions for stopping Cymbalta and its failure to include adequate warnings that fully and accurately inform

users and physicians of the nature, frequency, severity, and/or duration of Cymbalta's withdrawal symptoms.

37. Plaintiff was prescribed Cymbalta on October 31, 2012. When she tried to stop taking it a few months later, she suffered severe withdrawal symptoms. Her Cymbalta withdrawal symptoms were so severe that she was hospitalized on December 20, 2012. She was put back on Cymbalta to try to alleviate the withdrawal symptoms. Early in 2013, she discontinued Cymbalta for good.

38. At all times relevant, Lilly knew or should have known that Cymbalta is inherently dangerous and unsafe when used in the manner instructed and provided for by Lilly.

39. If Lilly had adequately, accurately and properly warned about the withdrawal symptoms associated with stopping Cymbalta, including accurately reporting their frequency, severity, and/or duration, Plaintiff's physician would not have prescribed the drug to Plaintiff; Plaintiff would have refused the drug; and/or Plaintiff's physician would have been able to more adequately, accurately and properly weigh and convey the risks and benefits of the drug in a way as to avoid Plaintiff's injuries and damages.

40. As a direct and proximate result of taking Cymbalta, Plaintiff suffered compensable injuries, including but not limited to the following:

a. physical, emotional, and psychological injuries;

b. past and future pain and suffering;

c. past and future mental anguish;

d. loss of enjoyment of life;

e. past and future medical and related expenses; and

f. loss of consortium and companionship.

FIRST CAUSE OF ACTION
NEGLIGENCE

41. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

42. Lilly owed to Plaintiff, and to other consumers and patients, a duty to exercise reasonable care in the design, formulation, sale, promotion, supply and/or distribution of Cymbalta, including the duty to ensure that the product carries adequate instructions and warnings.

43. Lilly was negligent in the design, testing, advertising, marketing, promotion, labeling, supply, and sale of Cymbalta in that it:

a. Failed to adequately warn about, and affirmatively misrepresented, the frequency, severity, and/or duration of Cymbalta's withdrawal symptoms;

b. Failed to adequately warn that Cymbalta could cause users to become physically dependent on the drug;

c. Failed to adequately warn that tapering is generally ineffective to avoid or mitigate withdrawal symptoms;

d. Failed to adequately instruct on a safe and effective method for tapering Cymbalta;

e. Failed to adequately inform that Cymbalta's design did not allow for effective tapering when discontinuing the drug;

f. Misled users by suggesting that Cymbalta withdrawal is rare;

g. Failed to adequately warn that the risk of Cymbalta withdrawal symptoms exceeds the risk of withdrawal symptoms posed by alternative treatment options;

h. Negligently marketed Cymbalta despite the fact that the risk of withdrawal symptoms was so high and the benefits of the drug were so questionable that no reasonable pharmaceutical company, exercising due care, would have placed it on the market;

i. Recklessly, falsely, and deceptively represented or knowingly omitted, suppressed, or concealed, material facts regarding the safety of Cymbalta to Plaintiff, the public, and the medical community;

j. Failed to comply with its post-manufacturing duty to warn that Cymbalta was being promoted, distributed, and prescribed without adequate warnings that fully and accurately inform users and physicians of the true frequency, severity, and/or duration of potential withdrawal symptoms; and

k. Was otherwise careless, negligent, grossly negligent, reckless, and acted with willful and wanton disregard for Plaintiff's rights and safety.

44. Despite the fact that Lilly knew, or should have known, that Cymbalta caused frequent and severe withdrawal symptoms, Lilly continued to market Cymbalta to consumers, including Plaintiff, without adequate instructions for stopping Cymbalta and without adequate warnings about the frequency, severity, and/or duration of the withdrawal symptoms. Lilly knew, or should have known, that Cymbalta users would suffer foreseeable injuries as a result of its failure to exercise ordinary care, as described above. Lilly knew or should have known that Cymbalta was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

45. Had Lilly provided adequate instructions for the proper method for stopping Cymbalta and/or adequate warnings regarding the frequency, severity, and/or duration of its withdrawal symptoms, Plaintiff's injuries would have been avoided.

46. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered significant injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

47. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SECOND CAUSE OF ACTION
INADEQUATE WARNING OR INSTRUCTION
(PRODUCT LIABILITY ACT – N.C.G.S. §99B-5)

48. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

49. Cymbalta was defective and unreasonably dangerous when it left the possession of Lilly, and Lilly acted unreasonably in failing to provide adequate warnings or instructions to alert consumers, including Plaintiff herein, of the dangerous risks and reactions associated with Cymbalta including, but not limited to, its propensity to cause injury, subjecting Plaintiff to risks that exceed the benefit of the product, including but not limited to a high risk of encountering severe and sustained withdrawal symptoms which include, among other things, headaches, dizziness, nausea, fatigue, diarrhea, paresthesia, vomiting, irritability, nightmares, insomnia, anxiety, hyperhidrosis, sensory disturbances, electric shock sensations, seizures and vertigo, as well as other severe adverse health consequences; failing to disclose that Cymbalta withdrawal symptoms rates were nearly double that experienced by placebo users and affected at least 44 percent of users who discontinued Cymbalta; notwithstanding Lilly's knowledge of an increased risk of these injuries; failing to provide physicians and patients with adequate instructions for stopping Cymbalta; failing to provide users and physicians with instructions or guidelines regarding a tapering regimen; and failing to warn physicians and patients that Cymbalta's design only allowed for doses to be decreased in 10 mg increments to a low dose of 20 mg.

50. At all times relevant herein, Lilly was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Cymbalta.

51. Lilly acted unreasonably in that at the time the Cymbalta product left their control, they failed to provide an adequate warning or instruction with the product, and thereby created an unreasonably dangerous condition that Lilly knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant, such as Plaintiff.

52. In the alternative, after the Cymbalta product left the control of Lilly, they became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable consumer, such as Plaintiff, and failed to take reasonable steps to give adequate warning or instruction to take other reasonable action under the circumstances.

53. At all times relevant herein, Lilly intended for the Cymbalta product to be used by members of the general public, including Plaintiff, and knew or should have known that the product would be used members of the general public, including Plaintiff.

54. Plaintiff's use of Cymbalta was reasonably foreseeable and was used in the manner for which it was intended by Lilly.

55. Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

56. Plaintiff, individually and through her physicians, reasonably relied upon the skill, superior knowledge and judgment of Lilly.

57. The warnings that were given by Lilly were inadequate, inaccurate, and/or ambiguous.

58. Lilly acted unreasonably in that the warnings that was given by Lilly failed to properly warn physicians of the increased risks associated with Cymbalta, subjecting Plaintiff to risks that exceeded the benefit of the product, including but not limited to a high risk of severe and sustained withdrawal symptoms which include, among other things, headaches, dizziness, nausea, fatigue, diarrhea, paresthesia, vomiting, irritability, nightmares, insomnia, anxiety, hyperhidrosis, sensory disturbances, electric shock sensations, seizures, vertigo, as well as other severe adverse health consequences; and failing to disclose that Cymbalta withdrawal side-effect rates were nearly double that experienced by placebo users and affected at least 44 percent of users who discontinued Cymbalta; failing to provide physicians and patients with adequate instructions for stopping Cymbalta; failing to provide users and physicians with instructions or guidelines regarding a tapering regimen; and failing to warn physicians and patients that Cymbalta's design only allowed for doses to be decreased in 10 mg increments to a low dose of 20 mg; notwithstanding Lilly's knowledge of an increased risk of these injuries;

59. Lilly had a duty to warn Plaintiff of the dangers associated with Cymbalta.

60. Had Plaintiff received adequate warnings regarding the risks of Cymbalta, he would not have used it.

61. As a direct and proximate result of Lilly's negligence, Plaintiff sustained injuries as described herein. As a result, Plaintiff suffers harm, economic loss, non-economic loss, and damages for aggravating circumstances and other losses in an amount to be proven at trial.

62. As a direct and proximate result of the said wrongful, willful and reckless acts and conduct of Lilly, Plaintiff suffered greatly and endured excruciating pain and suffering from her injuries, incurring substantial medical and other expenses as a result, for which Plaintiff is entitled to recover.

63. WHEREFORE**,** Plaintiff demands Judgment on this Count against Lilly, individually, jointly, severally, or in the alternative, for compensatory damages, exemplary damages, attorney's fees, costs of suit and all such other and further relief as the Court deems just and proper.

THIRD CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

64. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

65. Lilly owed a duty to Plaintiff and Plaintiff's physicians to convey and communicate truthful and accurate information about Cymbalta.

66. Lilly represented to Plaintiff, Plaintiff's physicians, and other members of the public and the medical community that Cymbalta was safe for use and that any withdrawal symptoms were no different, no worse, and no more frequent, than those of other similar products on the market. These representations were, in fact, false. Lilly's representations on the Cymbalta label suggested that withdrawal was rare, or that withdrawal symptoms occurred at a rate of approximately 1% or 2%, without mentioning the overall percentage of users who will experience withdrawal symptoms, which Lilly's own studies showed to be, at minimum, 44%.

67. Lilly was negligent in failing to exercise due care in making the aforesaid representations.

68. Lilly had a pecuniary interest in making said representations, which were made in order to expand sales and increase revenue from Cymbalta.

69. At the time said representations were made by Lilly, Plaintiff and Plaintiff's physicians took the actions herein alleged, and Plaintiff and Plaintiff's physicians were

ignorant of the falsity of Lilly's representations and reasonably believed them to be true. In justifiable reliance upon said representations, Plaintiff and Plaintiff's physicians were induced to, and did, use Cymbalta and attempt to discontinue Cymbalta. If Plaintiff and Plaintiff's physicians had known the actual facts, Plaintiff's injuries would have been avoided because Plaintiff's physician would not have prescribed the drug, Plaintiff would not have taken the drug, and/or the risk would have been conveyed to Plaintiff in a way so as to alter the prescription and avoid Plaintiff's injuries.

70. The reliance of Plaintiff and Plaintiff's physicians upon Lilly's representations was justified because the representations were made by individuals and entities who appeared to be in a position to know the true facts relating to risks associated with Cymbalta.

71. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered pecuniary losses including but not limited to past and future medical and related expenses.

72. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FOURTH CAUSE OF ACTION
FRAUD

73. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

74. As the United States Supreme Court stated in *Wyeth v. Levine,* "…it has remained a central premise of federal drug regulation that the manufacturer [of a prescription drug, such as Cymbalta] bears responsibility for the content of its label at all times. It is charged both with

crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." 555 U.S. 555, 571 (2009).

75. Lilly committed fraud by actively concealing material adverse information that was in its possession from its labeling and marketing of Cymbalta, including but not limited to, concealing the true frequency, severity and duration of Cymbalta's withdrawal symptoms and falsely represented the withdrawal risk associated with Cymbalta.

76. Lilly, through its clinical trial data, knew that, when it made the misrepresentations and/or omissions set forth herein, they were false, that patients and medical professionals would rely upon its misrepresentations and omissions, and that the misrepresentations were intended to cause patients like Plaintiff to purchase and ingest Cymbalta.

77. The specific acts of Lilly include the following:

a. Fraudulently suggesting that the withdrawal risk is rare, or occurred at a rate of approximately one (1) percent, when the overall rate of patients experiencing withdrawal, according to Lilly's own clinical trials, is high (at least 44.3% to 50%). Furthermore, an analysis of the data from Lilly's clinical trials reveals, with statistically significant results, that in comparison to stopping a placebo, stopping Cymbalta elevated the risk of specific withdrawal symptoms as much as 23-fold (i.e., nausea 23-fold, dizziness 17-fold, paresthesia 11-fold, irritability 9-fold, nightmares 8-fold, headaches 7-fold, and vomiting 4-fold);

b. Fraudulently omitting material information in its labeling and marketing concerning the severity of Cymbalta withdrawal including the fact that, in Lilly's clinical trials, between 9.6% and 17.2% suffered severe withdrawal (approximately 50% suffered moderate withdrawal);

c. Fraudulently omitting material information in its labeling and marketing concerning the duration of Cymbalta withdrawal. In fact, more than 50% of patients in the Cymbalta clinical trials continued to suffer from withdrawal symptoms two weeks after coming off the drug. Lilly did not monitor withdrawal beyond two weeks. Lilly was well aware that withdrawal symptoms could be protracted. For instance, the Cymbalta Summary of Product Characteristics" (SmPC) in Europe stated that, "in some individuals [withdrawal symptoms] may be prolonged (2-3 months or more)." The Practice Guideline for the Treatment of Patients With Major Depressive Disorder, Third Edition, published in 2010 (in which at least three Lilly consultants were on the working group and review panel) states under "Discontinuation syndrome" that "some patients do experience **more protracted** discontinuation syndromes, particularly those

treated with paroxetine [Paxil]" and "as with SSRIs, abrupt discontinuation of SNRIs should be avoided whenever possible. Discontinuation symptoms, **which are sometimes protracted**, are more likely to occur with venlafaxine [Effexor] (and, by implication desvenlafaxine [Pristiq]) than duloxetine [Cymbalta] (100) and may necessitate a slower downward titration regimen or change to fluoxetine." Given that Cymbalta's half-life falls between Effexor's and Paxil's – Effexor having the shortest, Cymbalta the second and Paxil the third – the Guideline is artfully worded;

d. Purposefully failing to use systematic monitoring with a withdrawal symptom checklist in the Cymbalta studies underlying Perahia's analysis, whereas in earlier Lilly-sponsored studies comparing Prozac to Paxil, Zoloft, and Effexor, Lilly systematically monitored withdrawal using a symptom checklist. Lilly was well aware of the withdrawal risk because it had orchestrated a marketing campaign differentiating Prozac from competitor antidepressants based on Prozac's comparatively long half-life. In fact, based on Cymbalta's half-life (the second shortest half-life between Effexor and Paxil), one would expect the true risk of withdrawal to be in a range between 66% and 78%. *See* Glenmullen, The Antidepressant Solution – A Step-by-Step Guide to Safely Overcoming Antidepressant Withdrawal, Dependence, and "Addiction" (2005);

e. Because Cymbalta's half-life is the second shortest and the closest to Effexor's, Lilly must have recognized that the risk of Cymbalta withdrawal was substantial, as confirmed by its own clinical trial data, and likely much worse as explained above. However, rather than being forthcoming about this important risk, Lilly instead chose to obscure the risk by using misleading language in its labeling and marketing;

f. Lilly obscured Cymbalta's true withdrawal risks by deflecting attention away from the Cymbalta-specific clinical trial data showing a clear and significant risk and focusing instead on other SSRIs and SNRIs. For instance, Lilly's label stated "During marketing of other SSRIs and SNRIs … there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt …" Lilly's use of "spontaneous" reports from "other SSRIs or SNRIs" is misleading given that approximately 40% to 50% of patients in Lilly's own clinical trials of Cymbalta reported adverse events. In using this language, Lilly misleadingly suggests that the withdrawal risks associated with other SSRIs and SNRIs are worse than Cymbalta's risks, which is the opposite of the truth – Cymbalta is one of the worst;

g. In addition to failing to warn about these known risks, Lilly utilized paid Key Opinion Leaders ("KOLs") to endorse the safety and efficacy of Cymbalta and assure prescribing doctors that Cymbalta's withdrawal risks were not as frequent, severe or protracted as they really are. Lilly did this through medical journal articles, treatment guidelines and medical seminars. For instance, Alan F. Schatzberg, a Lilly consultant and KOL who researched the phenomenon of antidepressant withdrawal as part of Lilly's campaign to promote Prozac in the 1990s, *see* paragraph 18 *supra*, wrote an article titled "Antidepressant Discontinuation Syndrome: Consensus Panel Recommendations for Clinical Management and Additional Research," J. Clin Psychiatry, 2006; 67 (suppl 4), two years after Cymbalta came on the market.

However, the article makes no mention of Cymbalta withdrawal or the fact that Lilly's own trials established withdrawal risks that were greater than those Lilly chose to include in the Cymbalta label;

h. Similarly, the American Psychiatric Publishing Textbook of Psychiatry, Fifth Edition with a Foreword written by the same Lilly consultant and KOL, Dr. Schatzberg, published in 2008, makes no mention of Cymbalta nor the frequency, severity or duration of Cymbalta withdrawal. Indeed, the text states:

> Discontinuation symptoms appear to occur most commonly after discontinuation of short-half-life serotonergic drugs (Coupland et al. 1996), such as fluvoxamine [Luvox], paroxetine [Paxil], and venlafaxine [Effexor].

There is no mention of Cymbalta although it had been on the market for four years and has a shorter-half than either Luvox or Paxil. Indeed, it had the second shortest half-life next to Effexor;

i. Lilly also appears to have engaged in selective and biased publication of its clinical trials of Cymbalta. In a recent study published in the New England Journal of Medicine, researchers obtained clinical trials for antidepressants (including Cymbalta) that had been submitted to the FDA and compared them with studies that had been published. The authors found that there was a "bias towards the publication of positive results" and that, "according to the published literature, it appeared that 94% of the trials conducted were positive. By contrast, the FDA analysis shows that 51% were positive." The authors found that, as a result of such selective publication, the published literature conveyed a misleading impression of Cymbalta's efficacy resulting in an apparent effect-size that was 33% larger than the effect size derived from the full clinical trial data. *See* Erick H. Turner et al., Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy, 358 NEW ENG. J. MED. 252 (2008).

78. When the above representations and/or omissions were made by Lilly, it knew those representations and/or omissions to be false, or willfully and wantonly and recklessly disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by Lilly with the intent of defrauding and deceiving the public and the prescribing medical community and with the intent of inducing the public to take Cymbalta and the medical community (including Plaintiff's physician) to recommend, prescribe, and dispense Cymbalta to their patients without adequate warning.

79. At the time the aforementioned representations or omissions were made by Lilly, and at the time Plaintiff purchased and began to ingest Cymbalta, Plaintiff was unaware of the falsity of Lilly's representations and/or omissions and reasonably relied upon Lilly's representations and omissions.

80. In reliance upon Lilly's representations and/or omissions, Plaintiff was induced to take Cymbalta and suffered significant withdrawal side effects.

81. Lilly's motive in failing to advise physicians and the public of Cymbalta's withdrawal risks was financial gain along with its fear that, if accompanied by proper and adequate information, Cymbalta would lose its share of the antidepressant market.

82. At all times herein mentioned, the actions of Lilly, its agents, servants, and/or employees were wanton, grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Plaintiff in particular and to the general public in that Lilly did willfully and knowingly place the dangerous and defective drug Cymbalta on the market with the specific knowledge that it would be sold to, prescribed for, and used by members of the public and without adequate instructions for use.

83. Punitive damages would be particularly appropriate for Lilly in this case given that fraud and concealment appear to be a part of its modus operandi. Since the 1980s, Lilly has had an ongoing history of concealing serious side effects associated with its drugs and illegally promoting its drugs. For example, in 1985, Lilly and one of its officers pled guilty to multiple criminal counts of violating the Food Drug and Cosmetic Act ("FDCA") arising out of Lilly's concealment of serious liver and kidney dysfunctions associated with its arthritis drug Oraflex. In 2009, Lilly agreed to plead guilty and pay $1.415 billion to the federal government for illegally promoting Zyprexa. This resolution included a criminal fine of $515 million, which, at the time,

was the largest settlement ever in a health care case, and the largest criminal fine for an individual corporation ever imposed in a United States criminal prosecution of any kind.

84. At *all time*s relevant herein, Lilly's conduct was malicious, fraudulent, and oppressive toward Plaintiff in particular and the public generally, and Lilly conducted itself in a willful, wanton, and reckless manner. Despite Lilly's specific knowledge regarding Cymbalta's withdrawal risks as set forth above, Lilly deliberately recommended, manufactured, produced, marketed, sold, distributed, merchandised, labeled, promoted, and advertised Cymbalta as being safe, with minimal withdrawal risks.

85. All of the foregoing constitutes an utter, wanton, and conscious disregard of the rights and safety of a large segment of the public. Thus, Lilly is guilty of reckless, willful, and wanton acts and omissions which evidence a total and conscious disregard for the safety of Plaintiff and others which proximately caused the injuries described herein. Therefore, Plaintiff requests punitive and exemplary damages in an amount to be determined at trial to deter Lilly from continuing its conscious disregard of the rights and safety of the public at large and to set an example so Lilly – as well as other similarly situated drug manufacturers – will refrain from acting in a manner that is wanton, malicious, and in utter, conscious disregard of the rights of a large segment of the public.

86. As a direct and proximate result of Lilly's false representations and/or omissions, Plaintiff has suffered serious injury, incurred and will in the future incur expenses, lost income and sustained other damages, including but not limited to pain and suffering, emotional distress, sorrow, anguish, stress, shock and mental suffering.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

87. Plaintiff incorporates by reference, as if fully set forth herein, all other paragraphs of this Complaint.

88. Lilly made numerous representations, descriptions, and promises to Plaintiff regarding the frequency, severity and/or duration of withdrawal symptoms caused by ceasing to take Cymbalta. Accordingly, Lilly expressly warranted that Cymbalta had a low or rare incidence of withdrawal symptoms.

89. As described herein, Plaintiff suffered injuries as a direct and proximate result of Plaintiff's discontinuation of Cymbalta.

90. At the time of Plaintiff's use of Cymbalta and resulting injuries, the Cymbalta he was taking was in essentially the same condition as when it left the control and possession of Lilly.

91. At all times relevant, the Cymbalta received and used by Plaintiff was not fit for the ordinary purposes for which it is intended to be used in that, *inter alia*, it posed a higher risk of withdrawal symptoms – of greater duration and severity – than other similar products available in the market.

92. Plaintiff's injuries were due to the fact that Cymbalta was in a defective condition, as described herein, rendering it unreasonably dangerous to Plaintiff.

93. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered significant injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur

medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

94. WHEREFORE, Plaintiff demands judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for judgment against Lilly as follows:

a. Judgment in favor of Plaintiff and against Lilly, for all damages in such amounts as may be proven at trial;

b. Compensation for economic and non-economic losses, including but not limited to, past and future medical expenses, medical monitoring, out-of-pocket expenses, past and future physical pain and mental anguish, past and future physical impairment, past and future loss of companionship and consortium, and past and future loss of household services, in such amounts as my be proven at trial;

c. Past and future general damages, according to proof;

d. Any future damages resulting from permanent injuries;

e. Psychological trauma, including but not limited to mental anguish, mental distress, apprehension, anxiety, emotional injury, psychological injury, depression, and aggravation of any pre-existing and/or underlying emotional or mental diseases or conditions;

f. Pain and suffering;

g. Loss of enjoyment of life;

h. Punitive and exemplary damages in an amount to be determined by trial;

i. Attorneys' fees and costs;

j. Treble damages;

k. Prejudgment and post-judgment interest;

l. Costs to bring this action; and

m. Any such other and further relief as the Court may deem just and proper in law or in equity.

DEMANDS FOR JURY TRIAL

Plaintiff respectfully requests a jury trial of all issues presented in this Complaint.

DATED: June 12, 2015

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CERTIFICATE OF SERVICE

I hereby certify that on June 12, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, and have verified that such filing was sent electronically using the CM/ECF system, which will send notice of such filing to all known counsel of record.

/s/Khesraw Karmand
Khesraw Karmand